

What is claimed is:

1. A method for the prevention, reduction or treatment of radiation injury comprising the step of orally administering to a human prior to expected exposure to radiation, during exposure to radiation or after exposure to radiation, a composition which comprises an amount of one or more compounds effective to regulate at least one of cell differentiation and cell proliferation which is effective, when administered orally, to regulate at least one of cell differentiation and cell proliferation, and an effective amount of one or more antioxidants.

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2. A method as claimed in claim 1, wherein the compound that regulates at least one of cell differentiation and cell proliferation is selected from the group consisting of vitamin D<sub>3</sub>, vitamin D<sub>3</sub> analogs, compounds that may be converted or metabolized into vitamin D<sub>3</sub> in the human body, and metabolites thereof.

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3. A method as claimed in claim 1, wherein the one or more compounds that regulate at least one of cell differentiation and cell proliferation are selected from the group consisting of: vitamin D<sub>3</sub>, 1, 25-dihydroxyvitamin D<sub>3</sub>, 1(S), 3(R)-dihydroxy-20(R)-(1-ethoxy-5-ethyl-5-hydroxy-2-heptyn-1-yl)-9, 10-seco-pregna-5(Z), 7(E), 10(19)-triene, and other vitamin D<sub>3</sub> derivatives which regulate at least one of cell differentiation and cell proliferation, and pharmaceutically acceptable salts thereof.

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4. A method as claimed in claim 1, wherein the one or more antioxidants are selected from the group consisting of: ascorbyl palmitate, ascorbic acid, vitamin A, vitamin A ester, vitamin E, vitamin E ester, α-lipoic acid carotenoid, chlorophyllin, chlorophyllin salt, coenzyme Q10, glutathione, green tea polyphenol, galangin, rutin, luteolin, morin, fisetin, silymarin, apigenin, gingkolides, hesperitin, cyanidin, citrin, curcuminoid, structurally similar derivatives thereof which exhibit antioxidant activity, and pharmaceutically acceptable salts thereof.

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5. A method as claimed in claim 1, wherein the compound that regulates at least one of cell differentiation and cell proliferation comprises vitamin D<sub>3</sub>, and the

antioxidant comprises ascorbyl palmitate, curcumin, vitamin A palmitate, vitamin E,  $\alpha$ -lipoic acid, green tea polyphenol, and chlorophyllin.

6. A method as claimed in claim 1 wherein the antioxidant comprises one or  
5 more antioxidant enzymes.

7. A method as claimed in claim 1, wherein the composition further comprises at least one compound selected from the group consisting of: flavonoids and flavonoid derivatives.

10 8. A method as claimed in claim 7, wherein the flavonoids and flavonoid derivatives are selected from the group consisting of: 1,2,3,6-tetra- $\alpha$ -gallyol- $\beta$ -d-glucose; 2'-o-acetylacetoside; 3,3',4-tri- $\alpha$ -methyl-ellagic acid; 6,3',4'-trihydroxy-

5,7,8-trimethoxyflavone; 6-hydroxy-luteolin; 6-hydroxykaempferol-3,6-dimethyl ether; 7-o-acetyl-8-epi-loganic acid; acacetin; acetoside; acetyl trisulfate quercetin; amentoflavone; apigenin; apin; astragalin; avicularin; axillarin; baicalein; brazilin; brevifolin carboxylic acid; caryophyllene; chrys-5,7-dihydroxyflavone; chrysoeriol; chrysosplenol; chrysosplenoside-a; chrysosplenoside-d; cosmoisin;  $\delta$ -cadinene; dimethylmussaenoside; diacylcirsimarin; diosmetin; dosmetin; ellagic acid; ebinin;

20 ethyl brevifolin carboxylate; flavocannibiside; flavosativaside; genistein; gossypetin-8-glucoside; haematoxylin; hesperidine; hispiduloside; hyperin; indole; iridine; isoliquiritigenin; isoliquiritin; isoquercitrin; jionoside; juglanin; kaempferol-3-

25 rhamnoside; kaempferol-3-neohesperidoside; kolaviron; licuraside; linarin; linarin; lonicerin; luteolin; luetolin-7-glucoside; luteolin-7-glucoside; luetolin-7-glucoronide; macrocarpal-a; macrocarpal-b; macrocarpal-d; macrocarpal-g; maniflavone; methy

scutellarein; naringenin; naringin; nelumboside; nepetin; nepetrin; nerolidol; oxyayanin-a; pectolinarigenin; pectolinarin; quercetagetin; quercetin; querimeritin; quercitrin; quercitryl-2'' acetate; reynoutrin; rhamnetin; rhoifolin; rutin; scutellarein; sideritoflavone; sophoricoside; sorbarin; spiraeoside; trifolin; vitexin; and wogonin.

30 9. A method as claimed in claim 7, wherein the flavonoids and flavonoid derivatives are selected from the group consisting of: quercetin, queretrin, myricetin, kaempferol and myrecetrin.

10. A method as claimed in claim 1, wherein the composition further comprises one or more ingredients selected from the group consisting of selenium and selenium compounds.

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11. A method as claimed in claim 1, wherein the composition further comprises one or more ingredients selected from the group consisting of organic germanium, Korean ginseng, an extract of Korean ginseng, American ginseng, an extract of American ginseng, Siberian ginseng and an extract of Siberian ginseng.

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12. A method as claimed in claim 1, wherein the composition further comprises one or more ingredients selected from the group consisting of anti-inflammatories, and B-complex vitamins.

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13. A method as claimed in claim 1, wherein a ratio of the amount of the compound that regulates at least one of cell differentiation and cell proliferation to the amount of antioxidant from about 200 IU per gram of antioxidant to about 3 million IU per gram of antioxidant.

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14. A method as claimed in claim 1, wherein a ratio of the amount of the compound that regulates at least one of cell differentiation and cell proliferation to the amount of antioxidant is from about 1800 IU per gram of antioxidant to about 1 million IU per gram of antioxidant.

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15. A method as claimed in claim 1, wherein a ratio of the amount of the compound that regulates at least one of cell differentiation and cell proliferation to the amount of antioxidant is from about 5000 IU per gram of antioxidant to about 200,000 IU per gram of antioxidant.

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16. A method as claimed in claim 1 further comprising the step of applying to an area of skin before, during or after exposure to radiation, a topical composition which comprises an amount of one or more compounds that regulate at least one of cell

differentiation and cell proliferation which is effective, when administered topically in the topical composition, to regulate at least one of cell differentiation and cell proliferation, and an effective amount of one or more antioxidants, formulated in a pharmaceutically acceptable topical carrier for a topical composition.

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17. A method as claimed in claim 16, wherein the pharmaceutically acceptable topical carrier comprises a sufficient amount of at least one non-U.S.P. hydrophilic ointment base to form a substantially topical composition.

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18. A method as claimed in claim 17, wherein the pharmaceutically acceptable topical carrier further comprises a sufficient amount of a panthenol selected from D-panthenol and DL-panthenol to promote penetration of one or more of the antioxidants and compounds which regulate at least one of cell differentiation and cell proliferation into the skin.

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19. A method as claimed in claim 16, wherein the pharmaceutically acceptable topical carrier comprises hydroxymethyl cellulose.

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20. A method as claimed in claim 16, wherein the pharmaceutically acceptable topical carrier comprises an acrylic copolymer dissolved in polyethylene glycol.

21. An oral composition for preventing, reducing or treating radiation injury comprising:

25 an amount of one or more compounds effective to regulate at least one of cell differentiation and cell proliferation which is effective, when administered orally, to regulate at least one of cell differentiation and cell proliferation, an effective amount of one or more antioxidants, and at least one of a pharmaceutically acceptable carrier for an oral composition, flavonoids, flavonoid derivatives, selenium, selenium compounds, anti-inflammatories, organic germanium, Korean ginseng, an extract of  
30 Korean ginseng, American ginseng, an extract of American ginseng, Siberian ginseng, an extract of Siberian ginseng and B-complex vitamins.

22. An oral composition as claimed in claim 21, wherein the composition further comprises at least one compound selected from the group consisting of: flavonoids and flavonoid derivatives.

5    23. A composition as claimed in claim 22, wherein the flavonoids and flavonoid derivatives are selected from the group consisting of: 1,2,3,6-tetra- $\alpha$ -gallyol- $\beta$ -d-glucose; 2'- $\alpha$ -acetylacetoside; 3,3',4-tri- $\alpha$ -methyl-ellagic acid; 6,3',4'-trihydroxy-5,7,8-trimethoxyflavone; 6-hydroxy-luteolin; 6-hydroxykaempferol-3,6-dimethyl ether; 7- $\alpha$ -acetyl-8-epi-loganic acid; acacetin; acetoside; acetyl trisulfate quercetin; 10 amentoflavone; apigenin; apiin; astragalin; avicularin; axillarin; baicalein; brazilin; brevifolin carboxylic acid; caryophyllene; chrysin-5,7-dihydroxyflavone; chrysoeriol; chrysosplenol; chrysosplenoside-a; chrysosplenoside-d; cosmoisin;  $\delta$ -cadinene; dimethylmussaenoside; diacylcirsimarin; diosmetin; dosmetin; ellagic acid; ebinin; ethyl brevifolin carboxylate; flavocannibiside; flavosativaside; genistein; gossypetin-15 8-glucoside; haematoxylin; hesperidine; hispiduloside; hyperin; indole; iridine; isoliquiritigenin; isoliquiritin; isoquercitrin; jionoside; juglanin; kaempferol-3-rhamnoside; kaempferol-3-neohesperidoside; kolaviron; licuraside; linarin; linarin; lonicerin; luteolin; luotonin-7-glucoside; luteolin-7-glucoside; luotonin-7-glucoronide; macrocarpal-a; macrocarpal-b; macrocarpal-d; macrocarpal-g; maniflavone; methy 20 scutellarein; naringenin; naringin; nelumboside; nepetin; nepetrin; nerolidol; oxyxayamin-a; pectolinarigenin; pectolinarin; querctagetrin; querctein; querimertrin; querctin; querctryl-2" acetate; reynoutrin; rhamnetin; rhoifolin; rutin; scutellarein; sideritoflavone; sophoricoside; sorbarin; spiraeoside; trifolin; vitexin; and wogonin.

25    24. A composition as claimed in claim 22, wherein the flavonoids and flavonoid derivatives are selected from the group consisting of: querctein, querctetrin, myricetin, kaempferol and myrecetin.

30    25. A composition as claimed in claim 21, wherein the composition further comprises one or more ingredients selected from the group consisting of selenium and selenium compounds.

26. A composition as claimed in claim 21, wherein the composition further comprises one or more ingredients selected from the group consisting of organic germanium, Korean ginseng, an extract of Korean ginseng, American ginseng, an extract of American ginseng, Siberian ginseng and an extract of Siberian ginseng.

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27. A composition as claimed in claim 21, wherein the composition further comprises one or more ingredients selected from the group consisting of anti-inflammatories, and B-complex vitamins.

10 28. A composition as claimed in claim 21, wherein the composition is in a form selected from the group consisting of tablets, capsules, lozenges, troches, hard candies, powders, sprays, elixirs, syrups, suspensions, solutions, mouthwashes, sprays, liquids, soft candy, gum drops, liquid filled candies, chewing gum bases, toothpastes, nasal aerosols or inhalants.

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29. A composition as claimed in claim 21, wherein a ratio of the amount of the compound that regulates at least one of cell differentiation and cell proliferation to the amount of antioxidant from about 200 IU per gram of antioxidant to about 3 million IU per gram of antioxidant.

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30. A composition as claimed in claim 21, wherein a ratio of the amount of the compound that regulates at least one of cell differentiation and cell proliferation to the amount of antioxidant is from about 1800 IU per gram of antioxidant to about 1 million IU per gram of antioxidant.

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31. A composition as claimed in claim 21, wherein a ratio of the amount of the compound that regulates at least one of cell differentiation and cell proliferation to the amount of antioxidant is from about 5000 IU per gram of antioxidant to about 200,000 IU per gram of antioxidant.

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32. An oral composition for preventing, reducing or treating radiation injury comprising:

non-carrier ingredients, and

a pharmaceutically acceptable oral carrier for an oral composition,

wherein every gram of non-carrier ingredients in the oral composition

comprises 3,800-4,800 IU of vitamin A palmitate; 2,400-7,200 IU of beta carotene;

5 240-480 IU vitamin D<sub>3</sub>; 95-300 IU of vitamin E in a form of alpha-tocopherol; 48-72 mg of alpha-lipoic acid; 280-580 mg of quercetin, 120-240 mg of ascorbyl palmitate; 4.5-7.2 mg of curcumin; 4.5-10 mg of green tea (C&P); 45-100 mg of chlorophyllin; 24-100 mg of carboxy ethyl sesquioxide of germanium and 180-540 mcg of superoxide dismutase.

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33. An oral composition as claimed in claim 32, further comprising:

beta carotene; curcumin; green tea polyphenol; chlorophyllin; and an antioxidant enzyme.

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34. An oral composition as claimed in claim 33, wherein the vitamin A is in a form of a vitamin A palmitate, and the antioxidant enzyme is superoxide dismutase.

20 35. An oral composition as claimed in claim 32, wherein a ratio of the amount of the compound that regulates at least one of cell differentiation and cell proliferation to the amount of antioxidant from about 200 IU per gram of antioxidant to about 3 million IU per gram of antioxidant.

25 36. An oral composition as claimed in claim 32, wherein a ratio of the amount of the compound that regulates at least one of cell differentiation and cell proliferation to the amount of antioxidant is from about 1800 IU per gram of antioxidant to about 1 million IU per gram of antioxidant.

30 37. An oral composition as claimed in claim 32, wherein a ratio of the amount of the compound that regulates at least one of cell differentiation and cell proliferation to the amount of antioxidant is from about 5000 IU per gram of antioxidant to about 200,000 IU per gram of antioxidant.